

REMARKS/ARGUMENTS

This is in response to the Office Action mailed January 15, 2005. Claims 22, 27, 40, 41, 44 and 45 have been amended to further particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims do not include any amendments for a purpose of limiting the inventive subject matter, but rather are intended to emphasize certain aspects of the invention already set forth in the claims. Support for the amendments can be found throughout the originally filed application, e.g., for claim 22, see page 10, line 3 and for claim 27, see page 10, line 27. Claims 40, 41, 44 and 45 have been amended to capitalize trade marked products. No new matter has been added. Claims 1-52 are presented for consideration, with claim 1, 47 and 48 being the independent claims.

Rejections Under 35 U.S.C. § 102 and 103

The Examiner has rejected claims 1, 2, 4-20, and 24-52 and claims 3, 21-23, under 35 U.S.C. §102(e) and §103(a), respectively, as being unpatentable over Pacetti et al., (US 2004/0063805).

The Pacetti et al., application was filed on September 19, 2002 and published on April 1, 2004. The present application was filed on September 16, 2003 as a continuation-in-part of International Patent Application No. PCT/US02/08039, filed on March 18, 2002 which claims priority to U.S. Provisional Application No. 60/276,089, filed on March 16, 2001.

The subject matter of claims 1-26, 28-35 and 37-52, to which the Examiner applies Pacetti et al., is supported in both the PCT application and the provisional priority application of the present application, either explicitly for claims 1-4, 6-8, 11-19, 21-26, 28-33, 38-46 and 48 or implicitly for claims 5, 9, 20, 34-35, 47 and 49-52. Therefore, the Pacetti et al., reference is not prior art to rejected claims 1-26, 28-35 and 37-52 and the Examiner is respectfully requested to withdraw the

rejection.

Moreover, the Examiner has rejected claims 27 and 36, under 35 U.S.C. §102(e) as being unpatentable over Pacetti et al., (US 2004/0063805). The Examiner asserts that "Pacetti et al. disclose a stent including a multi-layer coating as claimed comprising: a primer layer, a drug polymer layer and a topcoat layer, an intermediate membrane and a finishing coat layer wherein the primer coating including an adhesion/anchor polymer as claimed (see paragraph 13 to 54)."

However, Applicants contend that the invention as recited in claims 27 and 36 is distinct from Pacetti et al., which is primarily directed to an implantable medical device comprising a fluorinated polymer soluble in an organic solvent or a mixture of organic solvents (e.g., abstract and claims) for providing long term sustained drug release (e.g., paragraph 6). The coated stent of Pacetti et al., may include an optional primer layer, a drug-polymer layer, a topcoat layer, an optional intermediate membrane, and an optional finishing coating (e.g., paragraph 13).

In contrast, the present invention as set forth in claims 27 and 36 is directed to a stent having a coating comprising: (a) a primer layer of two or more polymers, and (b) a drug reservoir layer of two or more polymers comprising a drug stabilizing polymer, the primer layer polymers being distinct from the drug reservoir layer polymers, the drug reservoir layer further comprising one or more active agents. In presenting such a distinct coating composition, the invention provides a drug reservoir layer that protects and stabilizes the one or more active agents during sterilization and storage, and wherein the coating allows sufficient adhesion and flexibility to remain intact upon stent expansion and during a sustained period thereafter, and release of efficacious amounts of the active agent at the site of stent expansion.

More specifically, claim 27 requires the active agent be selected from one or more of tacrolimus, everolimus, and sirolimus, and claim 36 requires the active agent comprise heparin together with at least one of an anti-restenotic drug selected from the group consisting of paclitaxel, rapamycin, sirolimus, everolimus, tacrolimus, and combinations.

Pacetti et al., does not teach, disclose or suggest a coating having (a) a primer layer of two or more polymers, and (b) a drug reservoir layer of two or more polymers comprising a drug stabilizing polymer, the primer layer polymers being distinct from the drug reservoir layer polymers. In fact, Pacetti teaches away from the present invention by using one polymer that is the same in both the primer layer and the drug-polymer layer, e.g., Examples 1-3, 6 and 14.

Therefore, claims 27 and 36 are patentable because Pacetti does not disclose, teach or suggest a stent a coating having (a) a primer layer of two or more polymers, and (b) a drug reservoir layer of two or more polymers comprising a drug stabilizing polymer, the primer layer polymers being distinct from the drug reservoir layer polymers, as set forth by the present invention.

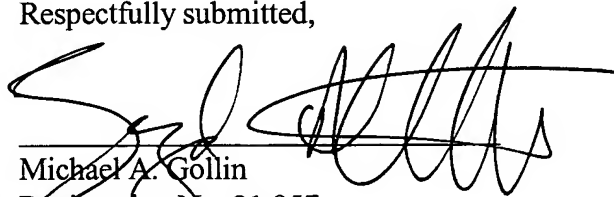
Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance indicating the allowability of claims 1-52 and that the application be passed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

Please charge any necessary fee or credit any overpayment in connection with this Information Disclosure Statement to Deposit Account No. 22-0261.

Respectfully submitted,



Michael A. Gollin
Registration No. 31,957
Zayd Alathari

Registration No. 42,256

VENABLE

P.O. Box 34385

Washington, D.C. 20043-9998

Telephone: (202) 344-4000

Telefax: (202) 344-8300

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